FEB 1 4 2000

Section 4: **510(k) Summary**

Company Name/Address:	Whiteside Biomechanics, Inc. 12634 Olive Blvd. St. Louis, MO 63141 P: 314-996-8540 F: 314-996-8543
Establishment Registration #:	1932213
Correspondent:	Debra Meyer
Device Name:	Whiteside Biomechanics Low-Profile Titanium Cable System
Proprietary Name:	Whiteside Biomechanics, Inc. Low-Profile Titanium Cable System
Common Name:	Surgical Cable
Classification Name:	Bone Fixation Cerclage
Classification Panel:	General & Plastic Surgery
Substantial Equivalence To:	Whiteside Biomechanics Low-Profile Cable System (K951844)

Device Description:

This implant consists of a 0.058" diameter cable, 23" in length, 20" length cable and 3" length lead and a cylindrical crimp with a transverse "through hole". The crimp, cable and lead cable are supplied as a single assembled unit. All three are preassembled in the manufacturing process. The cable is manufactured according to the material specifications for ASTM F136-96 in a 7 x 7 x 0.00064 wire construct. The crimp is also manufactured from ASTM F136-96.

A cable passer may be used to pass the free end of the cable around the bone. The free end is then passed through the transverse hole of the crimp in such manner as to have the free end emerge from the center of the crimp. A cable tensioner may be used to achieve a desired cable tension a which time the surgeon uses a crimper/cutter to crimp near the middle of the "through hole" and cuts the free end from the crimp.

Device Intended Use:

a) General orthopedic uses.

b) Trochanteric reattachment.

c) Fixation of long bone fractures-elbow, shoulder, ankle, patella.

d) Trauma fixation of shoulder, ankle and patella .

e) General spinal uses.

f) Spinal wiring.

Technological Comparison:

The Whiteside Biomechanics, Inc. Titanium Low-Profile Cable System is substantially equivalent to the predicate device. There are no different technological characteristics between the Whiteside Biomechanics Low-Profile Cable System and the Whiteside Biomechanics, Inc. Titanium Low-Profile Cable System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2000

Ms. Debra R. Meyer
Whiteside Biomechanics, Inc.
12634 Olive Boulevard
St. Louis, Missouri 63141

Re: K993903
Trade Name: Whiteside Biomechanics Low-Profile
Titanium Cable System
Regulatory Class: II
Product Code: JDQ
Dated: November 12, 1999
Received: November 16, 1999

Dear Ms. Meyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 10: Indications for Use

Device Intended Use:

a) General orthopedic uses.

b) Trochanteric reattachment.

c) Fixation of long bone fractures-elbow, shoulder, ankle, patella.

d) Trauma fixation of shoulder, ankle and patella .

e) General spinal uses.

f) Spinal wiring.

MRD for JED

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993903

Prescription Use X
(Per 21 CFR 801.109)